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10/764,674	01/23/2004	David G. Quinn	5935/83	9464

7590 09/20/2007
Brinks Hofer Gilson & Lione
P.O. Box 10395
Chicago, IL 60610

EXAMINER

WACHTEL, EMILY L

ART UNIT	PAPER NUMBER
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3709

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09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/764,674

Applicant(s)

QUINN, DAVID G.

Examiner

Emily Wachtel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 23, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,15-22 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-10,14 and 23-26 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :October 16, 2006 and November 11, 2004.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, 7-14, 23-26 drawn to a catheter assembly classified in class 604 subclass 528
 - II. Claims 5-6 drawn to a stylet subassembly classified in class 604 subclass 164.01
 - III. Claims 15-22, 27-29 drawn to a method of catheter insertion classified in class 604 subclass 516

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the catheter assembly of claims 1, 7, and 23 do not require the particulars of the stylet subcombination such as a sleeve fitting with an axial passage extending longitudinally from end-to-end. The subcombination has separate utility such as use with an endotracheal tube.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or

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divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Inventions (I and II) and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed in I and II can be used to practice a materially different process than that in III. For example the apparatus can be used in a process in conjunction with an endoscope.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Richard Lione on August 29, 2007 a provisional election was made without traverse to prosecute the invention of the catheter assembly claims 1-4, 7-14, and 23-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-6, 15-22, and 27-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

1. The abstract of the disclosure is objected to because of the following informality: the word --faulitates -- in line 10 is a misspelling, the word --facilitates-- should be inserted.

Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities:

Page 1 [0003] --length, however. This-- should read --length, however, this--

Page 3 [0013] -- 8Fr -- should be removed and -- 8 French (Fr) -- should be inserted

Page 5 [0033] [0035] -- flouroscopy -- should be removed and -- fluoroscopy -- should be inserted.

Page 7 [0055] insert --at line 2-2 of FIG. 1--after --FIG. 1--

Page 7 [0056] insert --at line 3-3 of FIG. 2 --after --FIG. 1--

Page 10 [0093] -- French (Fr) -- should be removed and -- Fr-- should be inserted with regards to the correction made on page 3, this way the abbreviation is explained upon its initial use.

Page 11 [0099] -- its stylet 28-- is referred to with reference to second stylet subassembly 16. In [0096] the stylet is given the number designation of 40 and the sleeve is number 28. Please make the appropriate correction to clarify which component you are discussing.

Page 13 [0107] -- single stylet 282-- is referred to, however, no such numbered component exists in FIG. 30. I believe the desired component is --single stylet 232--.

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Page 13 [0111] and Page 14 [0113] -- coil section 336-- is referred to, however, no such numbered component exists in the FIGS. 36-39. I believe the desired component is -- coil section 346--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 23, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Eidenschink et al. (U.S. Patent 6,746,466 B2) as evidenced from teaching in Bodicky et al. (U.S. Patent 5,665,064).

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Concerning claims 1, 23, and 25, Eidenschnick et al. teaches two wires extending into a catheter tube from the proximal end and being independently movable longitudinally within the catheter. (Fig. 1A and Fig. 6 elements 44 and 46. In Fig. 1A the proximal end of the catheter is taken to be the end closest to reference numeral 20 and the distal end to be the end near reference numeral 14. This is consistent with common practice. In Fig. 6 wire elements 44 and 46 are taken to be independently movable longitudinally within the catheter because they are releaseably connected to wire management system 111.) While guidewires (44,46) are not characterized by the Eidenschnick et al. tube stylets, nonetheless, the claimed stylets are taken to be embraced by the wires. Bodicky et al. is cited as evidence that the wires are commonly construed by one of ordinary skill in the art to be stylets because Bodicky et al. teaches a wire stylet inserted in the proximal end of a feeding tube, which is functionally equivalent to a catheter, and used to adjust its stiffness (Col. 6 lines 38-40). Also, providing evidence that an inherent quality of a wire stylet is to adjust stiffness. Thus, evidence is provided showing that a guide wire is commonly construed by one of ordinary skill in the art to be both a stylet as in claim 1 and a stiffening element as in claim 23.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eidenschink et al. (U.S. Patent 6,746,466 B2) as applied to claim 1 above and further in view of Quinn (U.S. Patent 5,810,787).

Eidenschnick et al. differs from claim 2 in that it does not teach a catheter tube that is a 8 Fr size tube. Eidenschnick et al. differs from claim 3 in that it does not teach a bolus on the distal end of the catheter. However, Quinn teaches the use of a size 8 Fr catheter tube, which can be used equally for all types of catheters (Col. 3 lines 18-22) that is used with a bolus (Figure 1, elements 20) located on the terminal end (Figure 1 element 15), which is functionally equivalent to the distal end of the catheter tube (Figure 1, elements 20 and 11, Col. 3 line 56). It would have been obvious to a person of ordinary skill in the art to use an 8 Fr tube in the catheter of Eidenschnick et al. because Quinn teaches the use of an 8 Fr tube which is suitable for all types of catheters (Col. 3 lines 18-22).

7. Claims 1, 4, 7 and rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) and in further view of Liu (U.S. Patent 6,547,761).

Burney et al. teaches a catheter assembly comprised of a catheter (Fig. 1 element 22), cannula (Fig. 1 element 24), and stylus (Fig. 1 element 26, Col. 1 lines 33-34). Each component is fit into a locking member (Fig. 1 elements 34, 44, 50) on its proximal end (The proximal end of each component is taken to be the end with the lock attached which is consistent with common practice.). These locking members are functionally equivalent to a catheter connector, or stylet fitting as recited in claim 7. When assembled all three locking members are releasably seated in/connected to each other. The locking member

of the cannula (Fig. 1 element 44) is seated in the locking member of the catheter (Fig. 1 element 34). The stylus locking member (Fig. 1 element 50) is connected to the locking member of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52). Burney et al. differs from claim 7 in that it teaches a stylet and a cannula, not two stylets. Though he does teach that the stylus and cannula are used to provide rigidity to the catheter. (Col. 1 lines 34-35). Liu discloses that a stiff cannula or stylet is used in a catheter interchangeably (Col. 1 lines 38-39). It would have been obvious to a person of ordinary skill in the art to substitute the cannula in Burney et al. with a stylet because Liu teaches that a cannula or a stylet are used in a functionally equivalent way and it would yield the predictable result of stiffening the catheter. With regards to claim 4 and claim 8, in Fig. 1 of Burney et al. the lower portion of locking member 44 near element 46 is taken to be the sleeve fitting for the primary stylet. Element 50 is taken to be the sleeve fitting for the secondary stylet. The upper portion of element 44 near element 52 is taken to be a sleeve fitting which connects the fittings of the two stylets. It is taken to be an intermediate sleeve fitting because element 50 does not fit entirely through element 44. Nor, does member 24 extend through element 44 to the fitting into the region of element 52. Thus, even though there is not a separate intermediate sleeve fitting, the region of member 44 near element 52 is taken to be a sleeve fitting which connects the fittings of the stylets and is integrated into the structure of element 44. Thus, the 'intermediate sleeve fittings' recited in this claim is taken to embrace the upper portion of element 44 in which element 50 is connected,

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8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) and Liu (U.S. Patent 6,547,761) as applied to claim 7 above, and further in view of Mar (U.S. Patent 4,771,778).

Burney et al. and Liu differ from claim 9 in that they do not teach a visible mark on a stylet located 12 inches from its stylet connector. Mar teaches a marker on a core wire, taken to be functionally equivalent to a stylet, disposed in a catheter (Fig. 2 elements 31 and 46). It would have been obvious to one of ordinary skill in the art to place a marker on the stylet in Burney et al. and Liu because Mar teaches that marks may be placed on the wire disposed in the catheter. It is advantageous because it is a radiopaque marker that can be viewed using fluoroscopy and aids in observing the position the body (Col. 2 lines 59-60, Col. 4 lines 1-2). It would be a matter of obvious design choice for the location of the mark. The mark will be located as desired by the user depending on how they are going to use viewing the mark via fluoroscopy. Ultimately, the mark is still being used to aid the user in knowing the location, within the patient, of the item it is placed on. For this reason, positioning a mark approximately 12" from its stylet connector would have been an obvious expediency in the art.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814 and Liu (U.S. Patent 6,547,761) as applied to claim 7 above, and further in view of Abrahamson et al. (U.S. Patent 5,382,238).

Burney et al. and Liu differ from claim 10 in that they do not teach a catheter tube containing two lumens. Abrahamson teaches a catheter tube with two lumens (Col. 3 line

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12). It would have been obvious to a person of ordinary skill in the art to use a double lumen catheter in the references of Burney et al. and Liu because Abrahamson et al. teaches using a double lumen catheter. This allows a wire stiffener to be inserted and then the catheter can be used in a conventional manner employing two lumens (Col. 4 paragraph 2).

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) and Liu (U.S. Patent 6,547,761) as applied to claim 7 above, and further in view of Quinn (U.S. Patent 5,810,787).

Burney et al. and Liu differ from claim 11 in that they do not teach a size 8 Fr single lumen catheter with a bullet nose bolus on its distal end. Quinn teaches a bolus with a bullet tip section located on the distal end of an 8 Fr tube (Fig. 1, Col. 3 lines 57 and 65). It would have been obvious to a person of ordinary skill in the art to use a catheter consisting of an 8 Fr tube with a bullet nose bolus on the distal end in Burney et al. and Liu because it is directly taught by Quinn to apply equally well to all types of catheters (Col. 3 lines 18-22).

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the reference set forth in numbered paragraph 10 and further in view of Frassica (U.S. 6,379,334) and Meng et al (U.S. Patent 6,506,181 B2).

Burney et al. and Liu differ from claim 14 in that they do not teach a catheter coated with a lubricant. Frassica teaches a water soluble lubricant being disposed on the distal tip of

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a catheter (Col. 17 lines 20, 23-24). Meng et al. teaches that a lubricious material may be disposed on the cavity of a catheter (abstract), putting it on the cavity of the catheter means it is disposed inside the catheter. It would have been obvious to a person of ordinary skill in the art to apply a lubricant inside and outside the catheter adjacent to the bolus in the references applied to claims 7 and 10 because Frassica teaches lubricating the distal tip of the catheter, also embodying the outside, this is where the bolus in the application is located, and Meng et al. teaches coating the inside surface of a catheter. There is incentive for lubricating the outside distal area of the catheter to make it more easily maneuvered inside the patient and inside the catheter tube so that the instruments moving inside the catheter, the stylets, move easily.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eidenschink et al. (U.S. Patent 6,746,466 B2) as applied to claims 23 above and further in view of Cruz et al. (U.S. Patent 5,571,093).

Eidenschink et al. differs from claim 23 in that it does not teach a catheter with a multiple lumen tube at its proximal end and a single lumen tube at its distal end. Cruz et al. teaches a catheter tube with two lumens at its proximal end and a single lumen at its distal end (Fig. 13). It would have been obvious to one of ordinary skill in the art to apply the disclosed catheter configuration to the reference in Eidenschink et al. because it allows for a stylet to pass through the lower lumen and through the bolus (Col.6 lines 14-15).

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13. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eidenschink et al. (U.S. Patent 6,746,466 B2) claim 25 above and further in view of Andersen (U.S. Patent 6,511,474 B1).

The references of Eidenschink et al. 25 differ from claim 26 in that they do not teach a bolus with a side port having an aperture through the nose for the passage of a guide wire. However, Andersen teaches a bolus with a fluid opening in the sidewall and an aperture through the terminal end which forms a stylet passage (Fig. 3, Col. 2 lines 65-67, Col. 3 lines 3-4). It would have been obvious to one of ordinary skill in the art to apply such a bolus to the references in Eidenschink et al. because the side port allows fluid to flow out of the catheter and into the patient and the stylet or guide wire is able to extend beyond the fluid passage in the sidewall.

Allowable Subject Matter

14. Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach a catheter assembly including an 8 Fr double lumen tube connected to a smaller single lumen tube by a bolus having a side port.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Wachtel whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

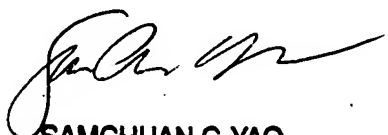
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily Wachtel
Patent Examiner
Art Unit 3709



EW 



SAMCHUAN C. YAO
SUPERVISORY PATENT EXAMINER